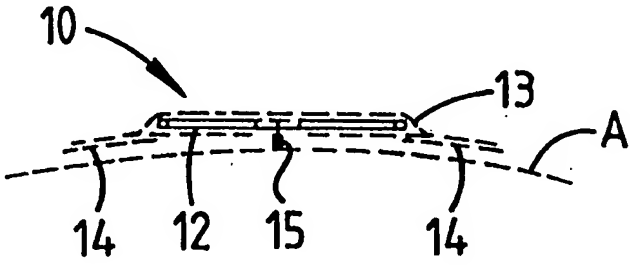


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(21) International Application Number: PCT/GB98/02765 (22) International Filing Date: 14 September 1998 (14.09.98) (30) Priority Data: 9719497.1 12 September 1997 (12.09.97) GB (71) Applicant (for all designated States except US): HOME DIAGNOSTICS UK LIMITED [GB/GB]; 9 Willow Road, Enfield, Middlesex EN1 3NF (GB). (72) Inventors; and (75) Inventors/Applicants (for US only): COURTENAY-LUCK, Nigel, Stephen [GB/GB]; 9 Willow Road, Enfield, Middlesex EN1 3NF (GB). CLARKE, Charles, John, Timothy [GB/GB]; 31 Birkbeck Road, Mill Hill, London NW7 4BP (GB). (74) Agent: GORDON, Richard, John, Albert; Barker Brettel, 10-12 Priests Bridge, London SW15 5JE (GB).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: REMOTE MONITORING OF PHYSIOLOGICAL CONDITION (57) Abstract <p>A system for remote monitoring the state of health of a living organism comprising a substrate (12) located within a water-proof disposable membrane (13) being provided with a pressure sensitive adhesive (14) extending peripherally of the membrane (13) for attaching the membrane (13) to skin (A) of the organism. The substrate (12) carries a transducer (15) for recording change of temperature of the organism. Signals indicative of temperature change are transmitted by electromagnetic radiation to a monitor for providing output indicative of the temperature change.</p> 		

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REMOTE MONITORING OF PHYSIOLOGICAL CONDITION

This invention relates to a system for remote monitoring the state of health of a living organism.

In order to counter the increasing costs of health care, investment in preventive medicine has become a major priority. One way of improving preventative medicine is to provide technologies which enable individuals, on a regular basis, to monitor parameters of their own health. This, in turn, will enable the detection of parameters of health and potentially fatal diseases at a sufficiently early enough stage to allow medical intervention which will ultimately lead to both an increase in the quality of life and life expectancy.

A problem associated with monitoring is that equipment available is not generally automatic and simple routine monitoring requires repetitive operator actions.

According to the present invention, there is provided a system for remote monitoring the state of health of a living organism comprising attachment means for attachment to the organism, the attachment means carrying means for generating signals indicative of a physiological condition of the

organism and means for transmitting the signals and the system comprising receiver means for receiving and processing the signals and for providing output indicative of the signals, wherein the signals are transmitted from the attachment means to the receiver means by electromagnetic radiation.

The invention thus provides a system in which the attachment means are attachable to the organism of an individual, there being no prerequisite for the person attaching the attachment means to have attained any particular knowledge or skill. When the attachment means has been attached to the organism and is in an operative mode, no intervention is required on the part of the individual or any other person to ensure that the system effectively monitors the state of health of the individual and the absence of any physical connection between the attachment means and the receiver means avoids any restriction on the free movement of the individual.

Also according to the present invention, there is provided attachment means for use in the system comprising a substrate carrying means for generating signals indicative of a physiological condition of the organism and means for transmitting the signals by electromagnetic radiation, the attachment means being adapted to be attached to the organism.

The attachment means comprising of at least a substrate carrying means for generating signals and means for transmitting the signals may be referred to as a "patch". Optionally, the substrate may be carried on a disposable membrane. This membrane may be provided with pressure sensitive adhesive for attaching the patch to the organism.

Therefore one, or a plurality of, attachment means may be provided independently of the receiver means.

The system may therefore, in its simplest form comprise at least one attachment means and a receiver means.

The substrate may carry a transducer for detecting change in the physiological condition of the organism and for generating signals indicative of the change, a source of electrical power, a transmitter powered by the source for transmitting electromagnetic radiation and an electrical circuit for controlling operation of the transmitter so that signals transmitted by the transmitter are indicative of the signals generated by the transducer.

The attachment means may include terminals or contacts for connecting to a supply of electrical power for renewing power removed from the power source.

The transducer may comprise a thermister which is adapted to change in resistance with temperature. Alternatively, it may comprise a temperature sensitive diode.

The transducer may comprise a part of a first RC circuit.

The electrical circuit may comprise a microcontroller. The microcontroller may operate by accessing a programme of instructions stored in an EPROM or EEPROM. This may be integral with the microcontroller. A clock may be provided which is connected to the microcontroller.

The microcontroller may be adapted to alternatively charge and discharge the capacitor in the first RC circuit. The microcontroller may measure the rate of charge and/or discharge of the capacitor in order to generate a signal indicative of the resistance of the transducer, and hence its temperature.

The microcontroller may further be adapted to charge and/or discharge a second (reference) RC circuit. A ratiometric comparison of time of charge and/or discharge of the second RC circuit with the first RC circuit may enable thermal drift in the electronic circuit to be compensated.

The microcontroller may be adapted to access an identifying code stored in memory (such as the EPROM or EEPROM). It may also be adapted to control the transmitter. The code may be

used as a unique signal or identifying code for any particular path.

The transmitter may comprise an RF transmitter, preferably operating at 418 MHZ. The RF transmitter sends information indicative of the measured value taken by the transducer to the receiver means. The signal may be transmitted as an FM signal.

The receiver means may comprise an RF receiver, which may also operate at 418 MHZ.

Two particularly noteworthy arrangements of the receiver means are envisaged.

In a first arrangement, the receiver means comprises a self-contained unit which is adapted to receive the signal transmitted by the patch and display a signal indicative of the measured parameter of a built in display or screen. The screen is preferably a flat-panel LCD display screen or LED segment display for displaying alphanumeric data.

The receiver means may be battery powered, with the battery in the receiver means self-contained unit. Alternatively, it may be mains powered or operate from another external supply.

It is envisaged that this first arrangement may be especially suited to the domestic market. For instance, where the transducer in the patch is a temperature sensor, the temperature value may be transmitted to the receiver means and displayed on the screen.

In the second arrangement, the receiver means may comprise a sub-unit which includes a transmitter means which enables a signal indicative of the value of the output signal received from the patch to be transmitted to a main base unit.

In both the first and second arrangements, the receiver means may include storage means for storing one or more patches. This may be in the form of a "docking" unit.

The patch may include a rechargeable power supply, such as a battery. In this case the receiver means may include a means for recharging the power supply when the patch is located on or in the storage means. It is then said to be "docked" on the receiver means.

The recharging means in the receiver means may include one or more electrical contacts which engage corresponding electrical contacts on the patch.

The patch may include a reed switch or other device which is normally closed when the attachment means ~~is~~ removed from

the receiver means. In this state, the power source in the patch is connected to the electrical circuitry in the patch.

When the patch is brought into contact with the receiver means the reed switch may be opened to isolate the electrical circuit in the patch from its power source. Simultaneously, this may initiate regarding to the power source by the receiver means. A magnet provided at the receiver means may be used to activate the reed switch.

An important and desirable feature of the system is for any one of a number of patches to be compatible with the receiver means without the need to specifically program a code into the receiver.

To this end, the patches may be adapted to emit an identifying code signal using the transmitter which can be received by the receiver and which is transmitted as soon as (or shortly after) the patch is removed from the receiver means. This may be an event recognised by the receiver either by the physical disconnection of the contacts to the patch or the receipt of a transmitted signal.

For example, each patch may be pre-programmed with an identifying code. When the attachment means is removed, this is detected by the receiver means which may then assign a receiving channel to that code. The channel will then only respond to a patch transmitting that code. Whenever the

patch transmits a signal, it is also adapted to transmit the code either before, after or during the transmission of the signal, and so different patches can easily be identified by the receiver means.

In a refinement, the code is not pre-programmed. Instead, the code may be comprised of a signal representative of the value measured by the transducer at the instant (or thereabouts) that it is removed from the receiver means. For example, this may correspond to the temperature of the transducer. Obviously, this will be a random value and so a random code is effectively generated each time the patch is removed from the receiver means. This code can then be used by the patch during all transmissions until it is powered down.

Another problem where more than one patch may be within transmission range of a receiver means is overlap of the signals transmitted which may prevent accurate information being discriminated.

In order to overcome the problem, it is proposed that the transmitter may transmit a signal indicative of the physiological condition of the organism at random intervals, or pseudo-random intervals.

In a preferred arrangement, this is achieved by only transmitting a signal if the information contained in the signal is "newsworthy".

By newsworthy, we means that the signal may only be transmitted if it has changed in value since the last value was transmitted, or if it has changed at a rate above a predetermined value.

For example, if the patch is adapted to measure temperature, a signal (and its identifying code) may only be transmitted if it has changed by a predetermined amount since it was last measured.

In a preferred arrangement, the electrical circuit includes a counter or clock, the transducer being interrogated on each clock pulse but a signal only transmitted if the measured value is "newsworthy". In this manner, it is highly unlikely that the transmission times for any two or more notches will overlap for any significant length of time.

As well as making it possible to prevent signals from different patches overlapping for any extended period, it also acts to conserve the power supply as the transmitter can effectively be turned off when not transmitting.

The transmitter of the patch may be based upon a SAW oscillator. It may transmit a signal as received on an input terminal from the electrical circuit. Each transmitted signals may comprise a burst of energy which may comprise an identifying code, a signal indicative of the physiological condition of the organism, and optionally a further identifying code.

The signal may be encoded in any one of a number of standard transmission protocols.

In another refinement, the receiver means may be adapted to generate an alarm signal (visual or audible for both) when a receiver means which was receiving signals from a patch does not receive a signal within a predetermined elapsed time. For example, an alarm can be initiated if the time gap between received signals exceeds a predetermined duration. This alarm could therefore isolate a fault in a patch or that the patch has been moved beyond the range of the receiver means. Applications where the patch is applied to a safety or secondary means in a hospital ward are envisaged.

Following is a description, by way of example only and with reference to the accompanying drawings, of one method of carrying the invention into effect.

In the drawings:-

Figure 1 is a functional diagram of a measuring and transmitting unit patch for an embodiment of a system in accordance with the present invention,

Figure 2 is a function diagram of a receiving and processing unit of the system,

Figure 3 is a block diagram of the receiving and processing unit,

Figure 4 is a diagrammatic plan view of an underside of the measuring and transmitting unit,

Figure 5 is a diagrammatic cross-section of the measuring and transmitting unit when located on an organism,

Figure 6 is a more details diagram illustrating the arrangement of components in an electrical current for a prototype of a patch,

Figure 7 shows an alternative patch electrical circuit, and

Figure 8 is a circuit diagram for a prototype receiver means which is compatible with the patches of Figures 6 and 7.

Referring now to the drawings, an embodiment of a system for monitoring the state of health of a living organism, such as

a human being, according to the present invention comprises one or more measuring and transmitting devices 10 (hereinafter referred to as patches) and a receiving and receiving and processing apparatus 11 (hereinafter referred to as receiver means).

The or each patch 10 comprises a substrate 12 located within a waterproof disposable membrane 13 of larger area than the substrate 12, a lower surface of the membrane 13 being provided with a pressure sensitive adhesive 14 extending peripherally of the membrane 13 in a margin beyond the periphery of the substrate 12 for attaching the membrane 13 to skin A of the organism. The substrate 12 carries a transducer 15, re-chargeable or disposable battery cells 16, a transmitting element 17 and micro-circuitry 18, 19 and 20 connecting the transducer 15, the battery cells 16 and the transmitting element 17 in circuit for timing, signal conditioning, encoding and radio-transmission of signals generated by the transducer 15. The substrate 12 also carries electrical contacts 21, whereby the device 10 may be connected to a charging device for charging the battery cells 16 (if re-chargeable), and a magnetically actuatable switch (not shown) for isolating the battery cell 16 when the device 10 is not in use.

The micro-circuitry includes a component 18 which conditions signals generated by the transducer 15 to a common format for communication; a component 19 for controlling, timing

and identification of signals to be transmitted from the transmitting element 17 and a transmitter 20 for routing signals to the transmitting element 17.

The receiver means 11 comprises a receiving element 22, a communications receiver 23, timing and decoding circuitry 24, processing circuitry 25, a keypad 26, a first interface connection 27 connected to an output of the processing circuitry 25, and interface circuitry 28 connecting a second output of the processing circuitry 28 connecting a second output of the processing circuitry 25 to a second interface connection 29.

The arrangement is such that radio signals are received by the receiving element 21 from one or more patches 10 and the signals are routed to the timing and decoding circuitry 24 which filters and decodes the received information, rejecting invalid information and presenting valid information in a standard format to the processing circuitry 25. Parameters for the processing of information received are set by inputs to the processing circuitry 25 from the keypad 26 or from external equipment via the first interface connection 27. The results of processing of the information received are passed via the interface circuitry 28 for local display by means of the indicator devices 30. Optionally, the results are passed to external equipment via the second interface connection 29.

The receiver means 11 also includes a dock 31 on an outer surface thereof for receiving a patch 10 whereby the device 10 may be stored awaiting use. The dock 31 includes terminals (not shown) for engaging the electrical contacts 21 of a device 10 when located in the dock 40 for effecting re-charging of the battery cells 16.

The or each patch 10 may be programmed during manufacture with a unique code signature and logic circuitry within the device 10 is set up and synchronised in accordance with a predetermined coding and control algorithm. The arrangement is such that data from the device 10 is transmitted in randomly spaced bursts as a means of saving battery power and reducing the probability, where more than one device 10 is in operation, that data from at least one of the devices 10 cannot be retrieved by the receiving and processing apparatus 11 because of overlap of data transmission from competing devices 10. Data transmitted from each transmitting element 17 starts with a code to identify the device 10 and is followed by one or more sequences of data and a checksum. As will be described hereinafter, the random nature of the signal transmission can be achieved by only transmitting, "newsworthy" information, or only predominantly newsworthy information.

It will be appreciated that the transducer 15 may be adapted to measure specific conditions of a living organism. For example, the transducer 15 may be adapted to measure change

of temperature or change of rate of heartbeat. It may therefore comprise a thermister.

It will also be appreciated that each transmitting and patch 10 may include more than one transducer 15.

Furthermore, it will be appreciated that the receiver means 11 may be extended by the addition of switch units or accessory modules. One such accessory module may provide facilities for handling further measuring and patches 10. Other accessory modules may be provided which extend the functionality of the base receiver means 11 to communicate with other systems (such as a baby alarm monitor) or to record and analyse the temperature data captured by the patches 10.

It will also be appreciated that each of the accessory modules may share the power supply, radio receiver and alarm unit of the receiver means 11.

The unique code signature of each measuring and patch 10 is indelibly printed on the outside of the patch 10 and may be separately supplied on a self adhesive label. When the patches 10 are not in use, they are placed on pads formed in the docks 40 of the receiver means 11 (and any accessory dock). The docking units may be identified using the extra self adhesive labels corresponding to the patches 10 that they accommodate. When the receiver means 11 is powered, it

detects the presence of the patches 10 by the flow of charging current and, by modulating the charging current, it one by one toggles the power on and off the patches 10 under its control. This causes the patches 10 to start their first transmission burst (start-up event) whose leading data constitute their signature. By recording this signature, the receiver means 11 notes the signature of each patch 10 and assigns to it one of its own channels. In the event of the patch 10 not transmitting, it follows that it is out-of-charge and the receiver means 11 warns the user and continues to charge the patch 10 through the electrical contacts 21. Periodically, it toggles the power of the patch 10 on and off to try to identify the patch 10.

In one arrangement, the patch 10 may not contain a predetermined unique code but may generate a random code on the first transmission sequence. As an example, this code may be dependent upon the initial value measured by the transducer. The patch 10 retains the code until returned to the base unit.

The very large variety of unique identity codes with which the patches 10 may be programmed at manufacture (or self-generated does) in conjunction with the automatic identification of patches 10 has especial advantages. It means that all patches 10 are interchangeable and may be acquired independently of the receiver means 11 as spares or replacements.

It is preferable for the patches 10 to be stored fully charged and ready for immediate use. The docks 40 incorporate a permanent magnet which opens the power switch (not shown) inside each measuring and transmitting patch 10. The removal of the patch 10 and subsequent closing of the power switch may initiate the first transmission sequence.

When the remote monitoring system is operable to record change of temperature, if the data is confirmed as valid, the receiver means 11 updates the appropriate temperature display 30. If the temperature is higher or lower than programmable limits, an alarm is enabled subject to three further conditions:

- (i) If the lower temperature condition is detected, the patch 10 has been operating for more than four minutes.
- (ii) If more than one minute has elapsed since a manual muting button was depressed.
- (iii) If the local alarm sounder has not been superseded by a remote extension module such as a baby alarm interface.

Other functions within the monitor include the enabling of the alarm in the event of valid transmissions from logged patches 10 not being received for a period exceeding five minutes.

The display 30 reports the reason for the alarm.

It will also be appreciated that, once a measuring and transmitting patch 10 has been attached to a living organism, it is desirable to establish that communication is effective between a patch 10 and the receiver means 11 without an operator having to wait for a transmission burst related to the automatic sequence. This is possible because of the magnetically actuatable power switch provided for each measuring and transmitting patch 10 since capacity for data communication is proved while the measuring and transmitting patch 10 is attached to the organism because a transmission burst can be forced out-of-sequence by actuating the power on switch within the patch 10, a wand-like accessory containing a permanent magnet being supplied as a component of the system.

Figure 6 comprises a circuit diagram for a prototype measuring and transmitting device 10 or patch. There are several differences in functionality between this patch and that shown in the preceding figures.

The device comprises a number of readily available discrete electronic components mounted on a substrate 12 comprising a printed circuit board (not shown).



The circuit comprises a measurement state 101 comprising a capacitor C1, a pair of resistors R1 and R2 and a thermister. A hybrid microcontroller 102, a STAMP2 device supplied by Parallax Inc., Rochlin, California, USA is connected to an EEPROM which stores operating code. This microcontroller is responsible for generating and storing the identifying codes, interrogating the measurement stage, and supplying transmission signals to the transmitter. A battery B1 is connected through a normally closed reed switch 103 to supply power to the microcontroller 102.

The microcontroller 102 is also connected to an external clock (not shown) in the form of an oscillator. The microcontroller controls power regulation and conservation.

Finally, the circuit also includes a transmitter device 105 which receives signals for the microcontroller 102 and transmits the signals in a coded form through a transmitter antenna 106.

Operation of the illustration circuit is as follows:

The measurement of temperature is achieved by discharging C1 through R1 by temporarily forcing the i/o at pin 12 high. It then reverts to its normal input (high impedance) state. The time taken for the input on pin 12 to go to a low state is measured. This may be the ~~time~~-taken for the input to

drop below a threshold voltage level (say 1/2 rail voltage for a CMOS device).

The process is then repeated, but this time the capacitor is charged through R2. R2 is a reference resistor with a value equivalent to the mid-range of temperature resistance of the thermister. The time taken for the capacitor to discharge is again measured. A ratio of the two times is taken to provide a ratiometric basis for deriving the temperature sensed the transducer. The one embodiment, as shown in Figure 6, the values are read by interpolating vectors stored in the microcontroller memory.

The measurement process is repeated at regular intervals as determined by the microcontroller 102. For example, the clock used to drive the microcontroller 102 can be used to set the time interval for temperature measurement.

Because the circuit is powered from a battery B1, it is important to reduce power consumption. In order to do so, the microcontroller 102 is adapted to analyse the measured value at regular intervals (ie each clock pulse) but only instruct the transmitter to transmit a signal if it meets a predetermined criteria. In such a case, the information is said to be "newsworthy".

The measured value ~~may~~ only be transmitted if it exceeds a ~~predetermined threshold~~, drops below a predetermined

threshold or deviates from a predetermined value by an excessive amount.

For example, when set up to measure temperature, the measured value may only be transmitted if it falls outside of an acceptable range of values.

In this manner, the duty cycle of the transmit signals can be varied so that a low duty cycle is used for "non-newsworthy" information and a higher duty cycle is used for "newsworthy" information.

In order to further reduce power consumption, the micro controller 102 is adapted to manage the power source and is normally in a sleep mode. It is awakened by counting pulses from its internal or external clock (a crystal for example). When awake a measurement sample is taken and its value compared with the previous value (or average previous value or other predetermined criteria). If the value is "newsworthy", the controller sends instructions to the transmitter 105. If not, it returns to its sleep mode and continues to count. As a back-up, a signal is transmitted at least once every, say, 30 minutes, regardless of whether or not it is newsworthy.

Another condition for a newsworthy value is if the microcontroller interprets the battery as being faulty, ie undercharged.

The transmitter shown in Figure 6 is a standard off the shelf hybrid circuit operating at substantially 418 MHz and is based on a SAW oscillator. Data is transmitted by first powering the transmitter 105 for a brief period (ie a few milliseconds) and then sending introductory data (from the microprocessor) to modulate the carrier to help lock the receiver. A buffer 107,108 is used from pin 14 of the STAMP device to allow the transmitter to take advantage of the higher (than the regulated voltage) unregulated battery voltage.

The microprocessor 102 transmits the measured signal by modulating the carrier at 1200 Baud. It also sends out a signature or identifying code to the transmitter. This signature is unique to the attachment means and remains constant at least during a session of use of the attachment means until it is returned to the receiver means for storage.

The basic operation of the prototype patch circuit has been set out above. There are several refinements to the functioning of the circuit.

One refinement helps the receiver to discriminate between information transmitted by one attachment means from information transmitted by a second attachment means.

Each patch stores (in memory) a unique identify code which is transmitted along with the measurement value. The code allows a receiver to identify a particular attachment means once it learns the identify code by looking for the presence of the identifying code in a received signal.

The signature may be stored in the attachment means as a permanent code which is programmed into memory. Alternatively, as in the case of the circuit shown in Figure 6, the microprocessor generates a code at random when it is first brought into use. For instance, this may be when the attachment means is removed from the receiver means. The code is generated by making an initial temperature measurement and using the signal generated thereby as its identify code. As the initial temperature will be virtually random, the chances of two attachment means used with the same receiver having the same code are relatively low. Once generated, the receiver locks onto this initial code. It is also stored in the memory in the attachment means for access by the microprocessor 102 at least until the power to the device is switched off. This will occur when the attachment means is returned to the receiver, when a magnet on the receiver activates the reed switch 103 in the attachment means.

To make the identifying signature distinct from actual temperature signals, ~~the~~ raw temperature measurement without ~~being~~ balanced by the ~~ratiometric~~ trimming is used.

Also during this start-up sequence or event, the microprocessor 102 instructs the transmitter 105 to transmit a signal representative of the "temperature" of its reference resistor R2. This signal, when detected by the receiver can be used to assess the gain of the individual attachment means and allow the receiver to apply a suitable trimming algorithm to all received signals.

An alternative patch circuitry is illustrated in Figure 7 of the accompanying drawings.

The patch is, in many respects, similar to the shown in Figure 6. The main difference is that the patch includes a bridge rectifier and contacts for rectifying a battery. The microprocessor is normally energised whilst it is being recharged by the receiver means. This is achieved by using a normally closed switch in the place of the original reed switch. The receiver can then de-energise the patch when docked and re-energise the patch to initiate transmission sequence whilst the patch remains on the receiver means.

Clearly, where a number of patches are associated with one receiver, and they each may send out a signal at a random time, the receiver must know when to listen for a signature. If not, it is possible that the receiver could accidentally become associated with other patches which are going thorough their start-up routine. Thus, synchronising

between the receiver and the attachment means during a start-up procedure is achieved by monitoring the recharge process.

The patch includes a rechargeable battery and is normally stored by being "docked" onto a storage means provided on the receiver. A circuit diagram illustrating a prototype receiver is shown in Figure 8. A pair of electrical contacts in the receiver engage with the contacts on the attached means to bring the battering circuit into contact with a charging circuit in the receiver.

At the time when the attachment means is "docked", a magnet in the receiver operates the reed switch in the attachment means. This switches the reed switch into a state where the battery is prevented from operating the microprocessor, transmitter etc. but is connected to the recharge circuit. When the attachment means is removed, the reed switch returns to its original stage to reconnect the battery. By monitoring this event, the microprocessor initiates its start-up routine (generating and transmitting a signature). Similarly, since the contacts are broken between the attachment means and received, the receiver knows when to look for the start-up routine.

In yet a further refinement, instead of generating a random code on each start-up sequence, the ~~code~~ code may be permanently stored in the EEPROM within the ~~patch~~ patch. This count, for

instance, be a code generated when the patch is used for the first time, and may be derived from an initial temperature measurement or some other random or pseudo-random event. This code will be retained in the EEPROM even if power is cut from the microconnector in the patch. If required, the code could be programmed into the memory in the patch during manufacture.

In the case of the circuit of Figure 7 of the accompanying drawings, the receiver itself takes control of the initial powering up by periodically dropping the charging voltage. This may result in the patch running through its power-on subscribing process as soon as the charging voltage is restored. Also, in the case of the prototype, when the patch is removed from the charging dock for deployment on the patient, the absence of the charging current is detected by the receiver so that it reverts to the temperature monitoring aspect of this program rather than the charging and subscribing functions.

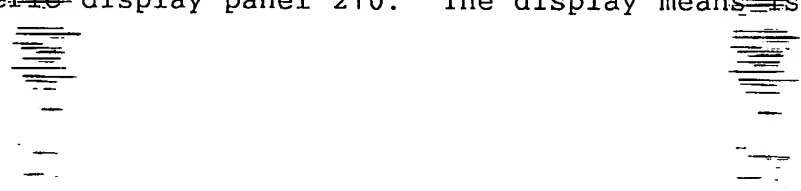
A similar function is achieved using a non-rechargeable battery as shown in Figure 6. Here the action of removing the patch from the docking station on the receiver simultaneously connects the patch's battery to its microcontroller which notifies the receiver that the subscribing transmissions are due to begin. One such approach again uses magnets and the reed switched on both the patch and the receiver's dock to signal the receiver

that the patch has been removed. Another uses a mechanical switch on the dock to signal the receiver while retaining the reed and magnetic switching for the patch battery (which may be packaged with a "remove for use" keeping magnet). Yet another uses a plastic ribbon originally packaged with the patch's battery to separate normally closed contacts that isolate the battery. The free end of the ribbon may be attached to a clamp on the receiver so that a tug on the ribbon as the patch is deployed prompts the receiver to listen for the signature.

A receiver 200 suitable for use with the patch shown in Figure 6 is illustrated in Figure 8. The receiver 200 comprises an antenna for receiving signals sent by a patch. Power for the receiver is supplied by connecting a twelve volt supply and ground to inputs 202 and 203 respectively. A regulator 204 steps this down to produce a 5 volt supply line.

A microcontroller 205, a STAMP 2 device, receives the output from the antenna for processing. An FM radio receiver chip 206 also receives the antenna output and is adapted to drive a signal strength meter 207. The microcontroller runs from the twelve volt supply, the chip 206 for the 5 volt rail.

The output from the microcontroller is connected to a display means 208 comprising a display driver ~~206~~ and an alphanumeric display panel 210. The display means ~~is~~ drive



by the microprocessor. An audible alarm unit 211 is also driven by the microprocessor and operates from the 5 volt rail.

In addition, the receiver means includes a battery charging circuit 212 which includes 214,215 for co-operation with the contacts on the patch. A magnet 213 is provided with the contacts in a storage means (docking bay) on the receiver.

More specifically, the receiver 200 is powered by a proprietary mains adapter connector to the contacts 202,203 and includes a number of sub systems. An 418 MHz fm radio receiver (proprietary available from RS Components), a 5v regulator for supplying the radio and displays, a serial LED display driver and associated 7-segment displays, a STAMP microcontroller (as per the transmitter), a piezo annunciator with a timer circuit that allows it to be muted by the user for a limited period before being re-enabled. The control panel of the receiver thus contains the mute button and four further buttons that set the minimum and maximum temperature limits for the alarm, a three digit display, a panel meter showing the radio signal strength, a pilot light and a 9-pin D type connector which is the accessories serial port.

In the circuit diagram of Figure 8, the EEPROM of the STAMP 2 microcontroller not only holds the program, but is also updated with the signature (if available) of the patch to

which it has been subscribed and any changes to the minimum and maximum alarm setting. It is also able to log any gathered temperature data. This is done by loading the data into memory in a first-in first-out manner so that the oldest data is rejected. These data are accessible by the serial port which is included in the receiver unit and provide the system with a means for loading the data into, for example, a PC, Palmtop computer or ticket printer in which it may be graphically displayed and filed as patient's records. With the addition of a real-time-clock it also allows the microcontroller to be programmed to sound alerts independently of temperature, for example, to prompt carers when it is time to administer medicine.

The Hybrid 418 MHz fm receiver may be an off-the-shelf item as are the displays, their driver and the annunciator. The sounder within the annunciator assembly has been augmented by a 555 timer that, in response to a button press, mutes the sounder for approximately one minute. It also contains a high brightness LED that flashes to serve as a visual alarm. The receiver has an auxiliary output for an analogue signal strength meter which provides the user with confidence that the radio link is established.

The STAMP2 205 receives data serially from the fm radio receiver 206, IC2, and transmits data serially to the MAX7219 display driver. It controls the patch charging relay, RL2, which is regularly actuated to modulate the

power to the patch thus causing it to transmit its signature each time the power is restored. The microcontroller also senses the presence of the patch on the charger dock by the charging current. The charging current causes a voltage drop across R5, which, after attenuation between R8 and R9, turns Q1. The rise in collector voltage is, after attenuating between R6 and R7, sampled by the microcontroller.

The STAMP2 also samples the state of the push buttons that set the alarm limits. Two of the buttons are concerned with setting the high and the low temperature limits and the other two buttons are concerned with increasing and decreasing the values.

The magnet provided in the receiver is adapted to open the reed switch in the patch so that the battery in the patch does not discharge when the receiver unit is itself not powered.

The STAMP2 is programmed initially to detect the presence of the patch on its charging dock. If one is found, the patch will be charged but periodically it will interrupt the charging and listen for the patch's signature. If it cannot receive one at this stage because of a fully discharged battery, the alarm sounds to warn of the flat battery (it may be manually muted with it recharging). As soon as there is sufficient charge in the patch's battery, the radio link

is established and the signature is recorded in the receiver's EEPROM. This enables the receiver's power supply to be interrupted without it needing to re-subscribe to an already-deployed patch.

If the STAMP2 cannot detect the patch on the storage means, it assumes it is deployed and listens out for the signature last recorded in the receiver's EEPROM. If it cannot hear this within 30 minutes of the last transmission, it sounds the alarm. While the correct signature is detected, the succeeding temperature data is logged and output to the Led display. If the temperature value is within the safe zone, the alarm is disabled.

The circuit of Figure 8 can be readily adapted to operate with a non-rechargeable patch by deleting the charging components 212. The sensing of the presence of the patch and its simultaneous power cycling for the purposes of subscribing the unique signature can be achieved magnetically or by mechanically actuated contacts as the patch is lifted clear of the docking station.

As described in the example, the patch may comprise a thin semi-rigid module, encapsulated within a waterproof membrane which can be held in intimate contact with a patient, for example in a hospital.

The transmitter may comprise a loop aerial printed onto the membrane which is suitable for the 418 MHz or 433.92 MHz transmitting ranges which are DT1 approved and MPT 1340 exempt.

Of course, the skilled man will appreciate that many of the features illustrated are optional, and that the circuits in Figures 6,7 and 8 are by way of example only.

Claims

1. A system for remote monitoring the state of health of a living organism comprising attachment means (10) for attachment to the organism characterised in that the attachment means (10) carries means (15) for generating signals indicative of a physiological condition of the organism and means (17) for transmitting the signals and the system comprises receiver means (11) for receiving and processing the signals which are transmitted from the attachment means (10) to the receiver means (11) by electromagnetic radiation.
2. A system according to Claim 1 characterised in that the attachment means (10) includes a substrate (12) which is carried on a disposable membrane (13).
3. A system according to Claim 2 characterised in that the disposable membrane (13) is provided with pressure sensitive adhesive (14) for attaching the membrane (13) to the organism.
4. A system according to Claim 2 or Claim 3 characterised in that the substrate (12) carries a transducer (15) for detecting change in the physiological condition of the organism and for generating signals indicative of

the change, a source (16) of electrical power, a transmitter (17) powered by the source (16) for transmitting electromagnetic radiation and an electrical circuit (18,19,20) for controlling operation of the transmitter (17) so that signals transmitted by the transmitter (17) are indicative of the signals generated by the transducer (15).

5. A system according to Claim 4 characterised in that the attachment means (10) includes terminals (21) for connecting to a supply of electrical power for renewing power removed from the power source (16).
6. A system according to Claim 4 or Claim 5 characterised in that the transducer (15) comprises a thermister which is adapted to change its resistance with temperature.
7. A system according to Claims 4, 5 or 6 characterised in that the transducer (15) comprises a part of a first RC circuit.
8. A system according to any one of Claims 4 to 7 characterised in that the electrical circuit (18,19,20) comprises a microcontroller adapted to access instructions stored in an EPROM or EEPROM.

9. A system according to Claim 8 as dependent on Claim 7 characterised in that the microcontroller is adapted to alternatively charge and discharge the capacitor in the first RC circuit and measure the rate of change and/or discharge of the capacitor in order to generate a signal indicative of the temperature of the transducer.
10. A system according to Claim 9 characterised in that the microcontroller is further adapted to charge and/or discharge a second (reference) RC circuit and make a ratiometric comparison of the time of charge and/or discharge of the second RC circuit with the first RC circuit.
11. A system according to any preceding Claim characterised in that the means (17) for transmitting comprises an RF transmitter.
12. A system according to Claim 11 characterised in that the receiver means (11) comprises an RF receiver.
13. A system according to any preceding Claim characterised in that the receiver means (11) comprises a self contained unit which is adapted to receive the signal transmitted by the transmitter means (17) and displays a signal indicative of the measured parameter on a built-in screen.

14. A system according to any preceding Claim characterised in that rectifying means is provided in the receiver means (11) which includes one or more electrical contacts which engage corresponding electrical contacts on the attachment means (10).
15. A system according to any preceding Claim characterised in that the attachment means (10) includes a reed switch is normally closed when the attachment means (10) is removed from the receiver means (11).
16. A system according to Claim 15 characterised in that when the attachment means (10) is brought into contact with the receiver means (11) the reed switch is opened to isolate the transmitting electrical circuit from its power supply and simultaneously to initiate recharging of the power supply by the receiver means (11).
17. A system according to any preceding Claim characterised in that the receiver means (11) includes storage means.
18. A system according to Claim 17 characterised by being adapted to perform a start-up event whereby an identifying code signal is transmitted using the transmitter means (17) which can be received by the receiver means (11) and which is transmitted as soon as (or shortly after) the attachment means (10) is removed from the receiver means (11).

19. A system according to Claim 18 in which a start-up event is recognised by the receiver means (11) detecting the physical disconnection of contacts on the attachment means (10) from contacts on the receiver means (11).
20. A system according to any one of Claims 8, 9 or 10 characterised in that the microcontroller is adapted to access an identifying code stored in memory.
21. A system according to Claim 20 characterised in that the identifying code is pre-programmed.
22. A system according to Claim 20 characterised in that the code comprises of a signal representative of the value measured by the signal generating means at the instant (or thereabouts) that the attachment means (10) is removed from the receiver means (11).
23. A system according to any preceding Claim characterised in that the transmitter means (17) is adapted to transmit a signal indicative of the physiological condition of the organism at random intervals, or pseudo-random intervals.

24. A system according to Claim 23 characterised in that a signal is transmitted if the information contained in the signal is "newsworthy".
25. A system according to Claim 24 in which information is newsworthy if it has changed in value since the last value was transmitted.
26. A system according to Claim 24 or Claim 25 in which information is deemed newsworthy if it has changed at a rate above a predetermined value.
27. A system according to any preceding Claim characterised in that the attachment means (10) carries a clock or counter and a signal indicative of the physiological condition is generated in each close pulse but a signal only transmitted if the generated value is "newsworthy".
28. A system according to any preceding Claim characterised in that the transmitter means (17) is based upon a SAW oscillator.
29. A system according to any preceding Claim characterised in that each transmitted signal comprises a burst of energy.

30. A system according to any preceding Claim characterised in that the receiver means (11) is adapted to generate an alarm signal when the receiver means (11) which was receiving signals from a transmitter means (17) does not receive a subsequent signal with a predetermined elapsed time.
31. A system according to any preceding Claim characterised in that the receiver means (11) is adapted to provide an alarm signal in the event that the period of time elapsed since a transmitter signal was received exceeds a predetermined time.
32. An attachment means (10) for use in the system of any preceding Claim comprising a substrate (12) characterised in that the substrate (12) carries means (17) for generating signals indicative of a physiological condition of the organism and means (17) for transmitting the signals by electromagnetic radiation, the attachment means (10) being adapted to be attached to the organism.

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FIG. 1

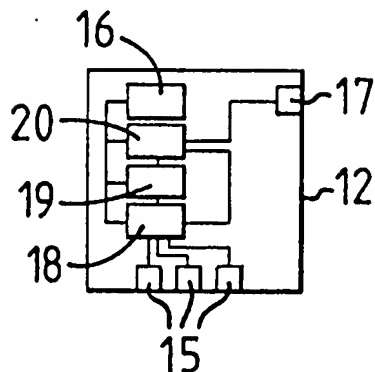


FIG. 2

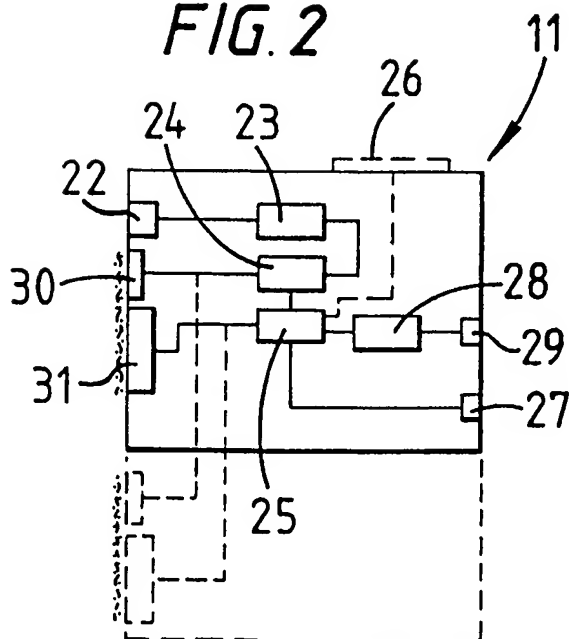


FIG. 3

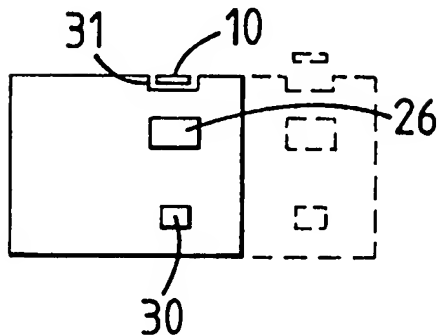


FIG. 4

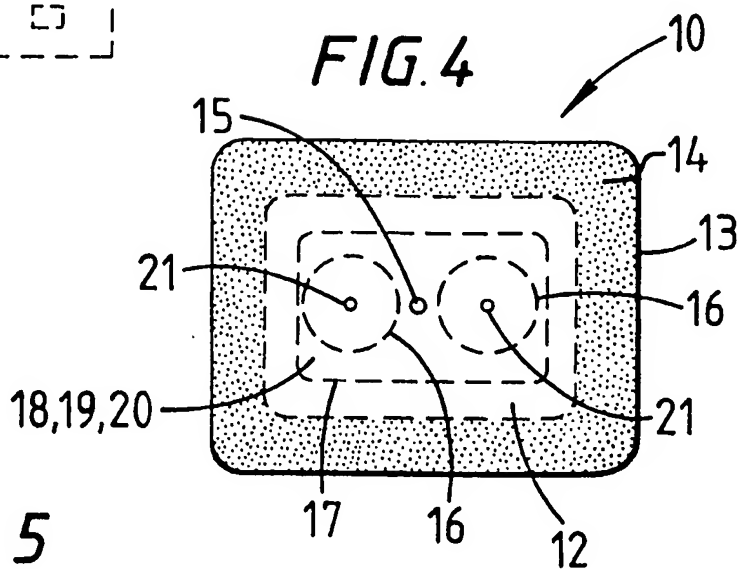
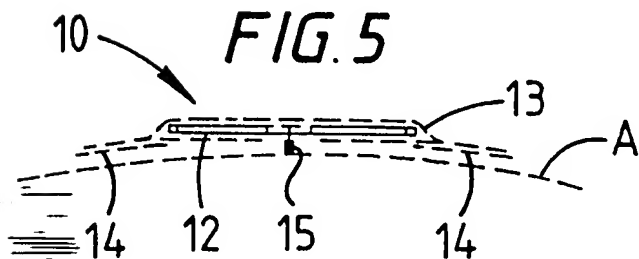
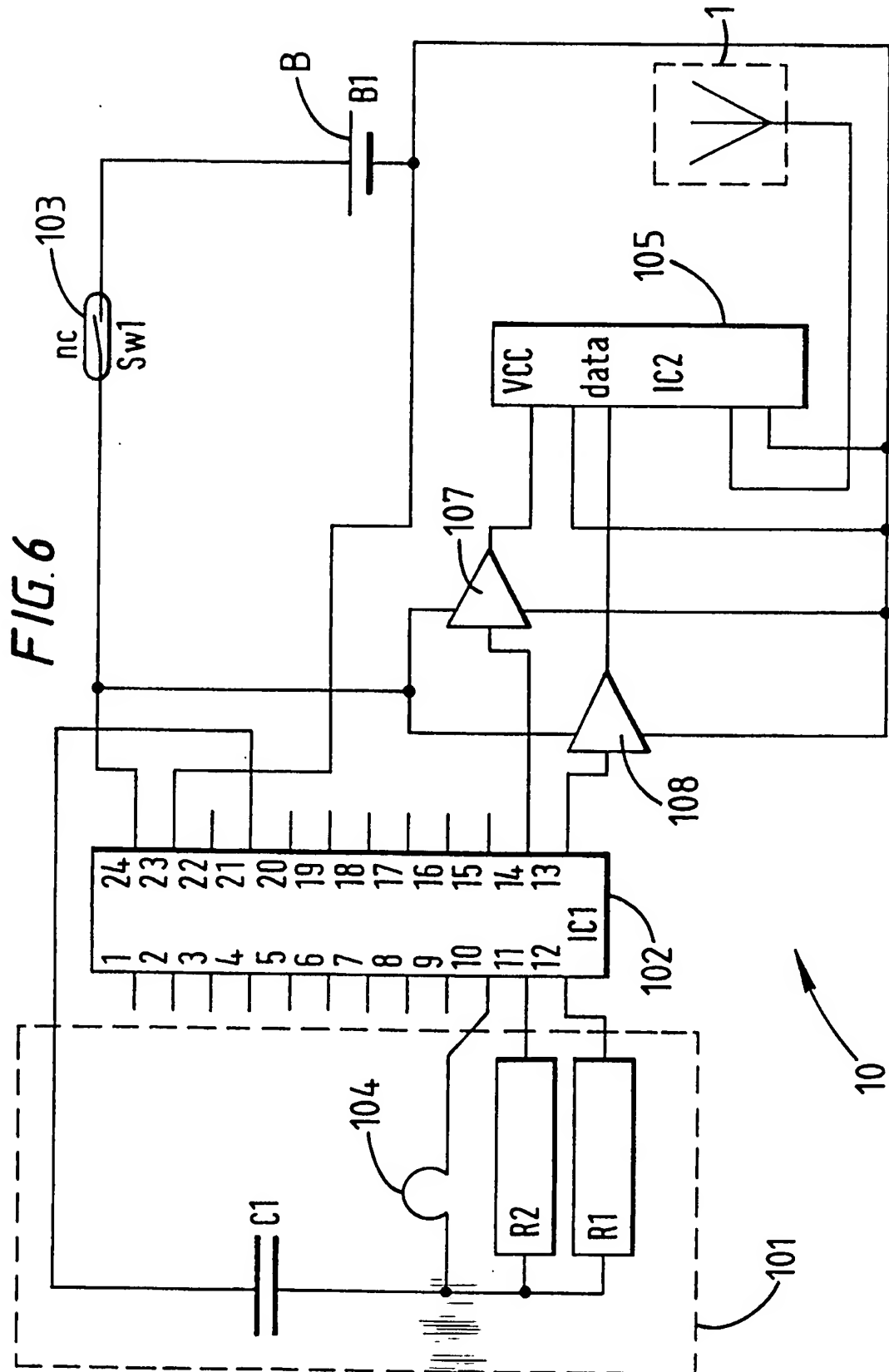


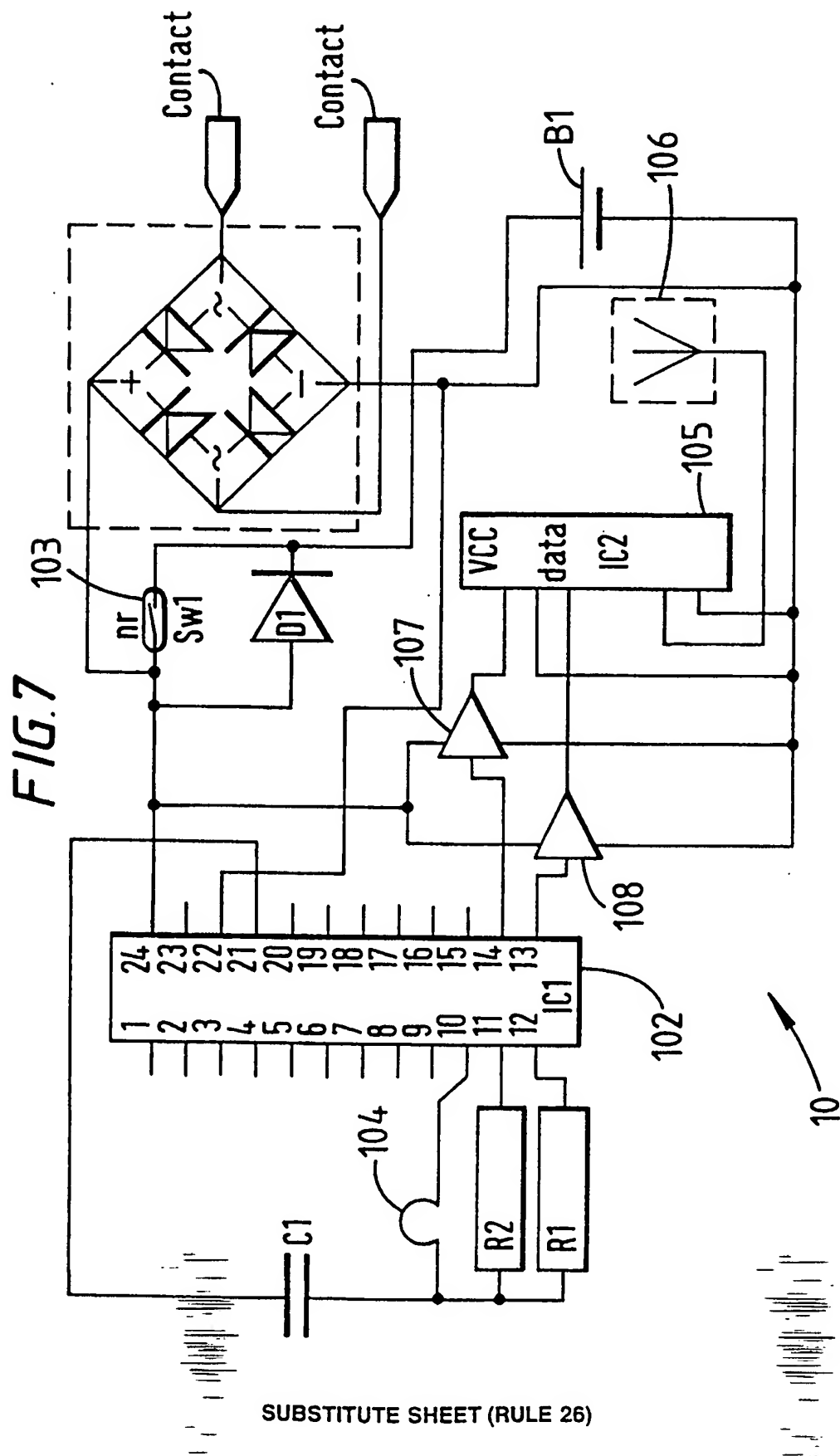
FIG. 5



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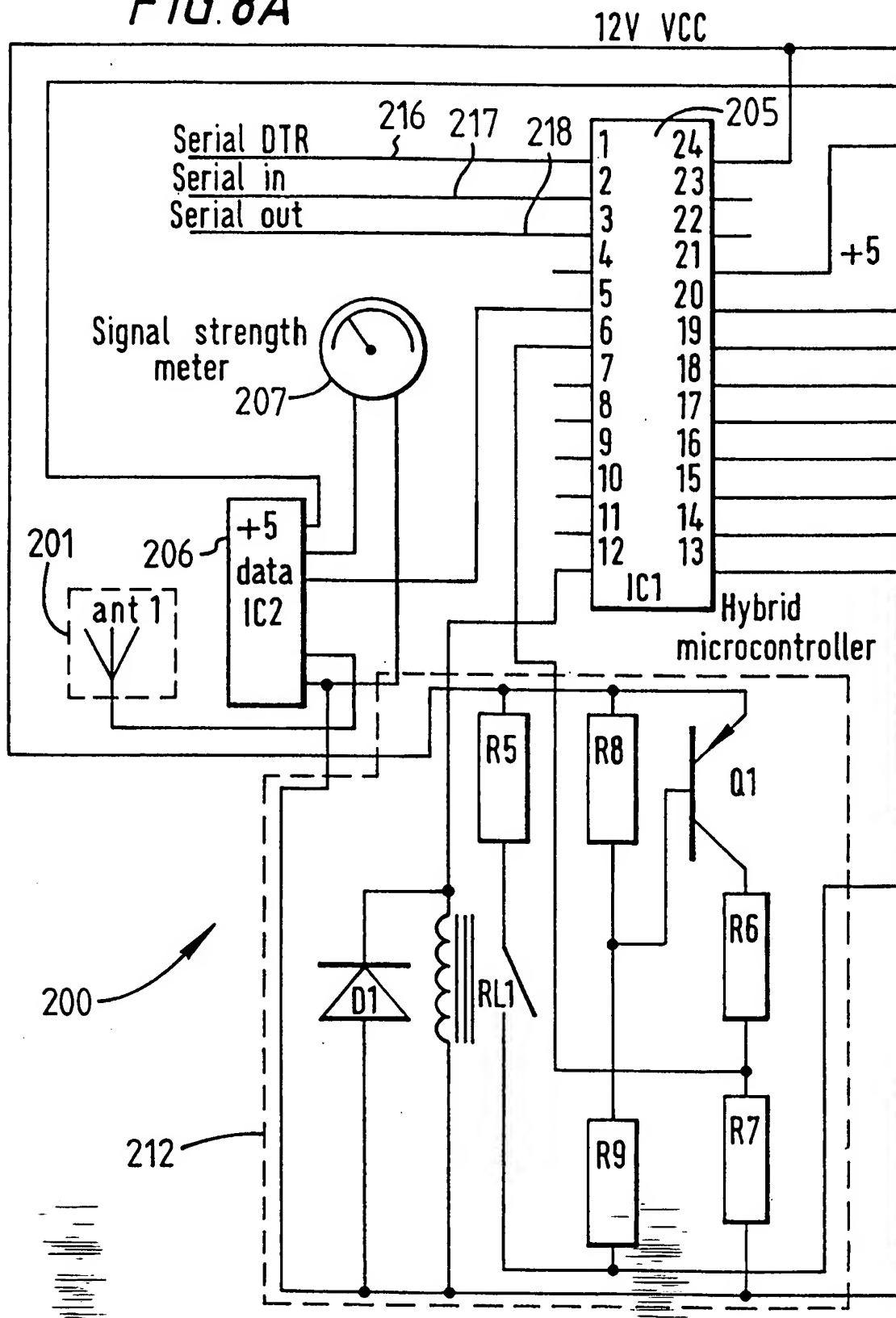


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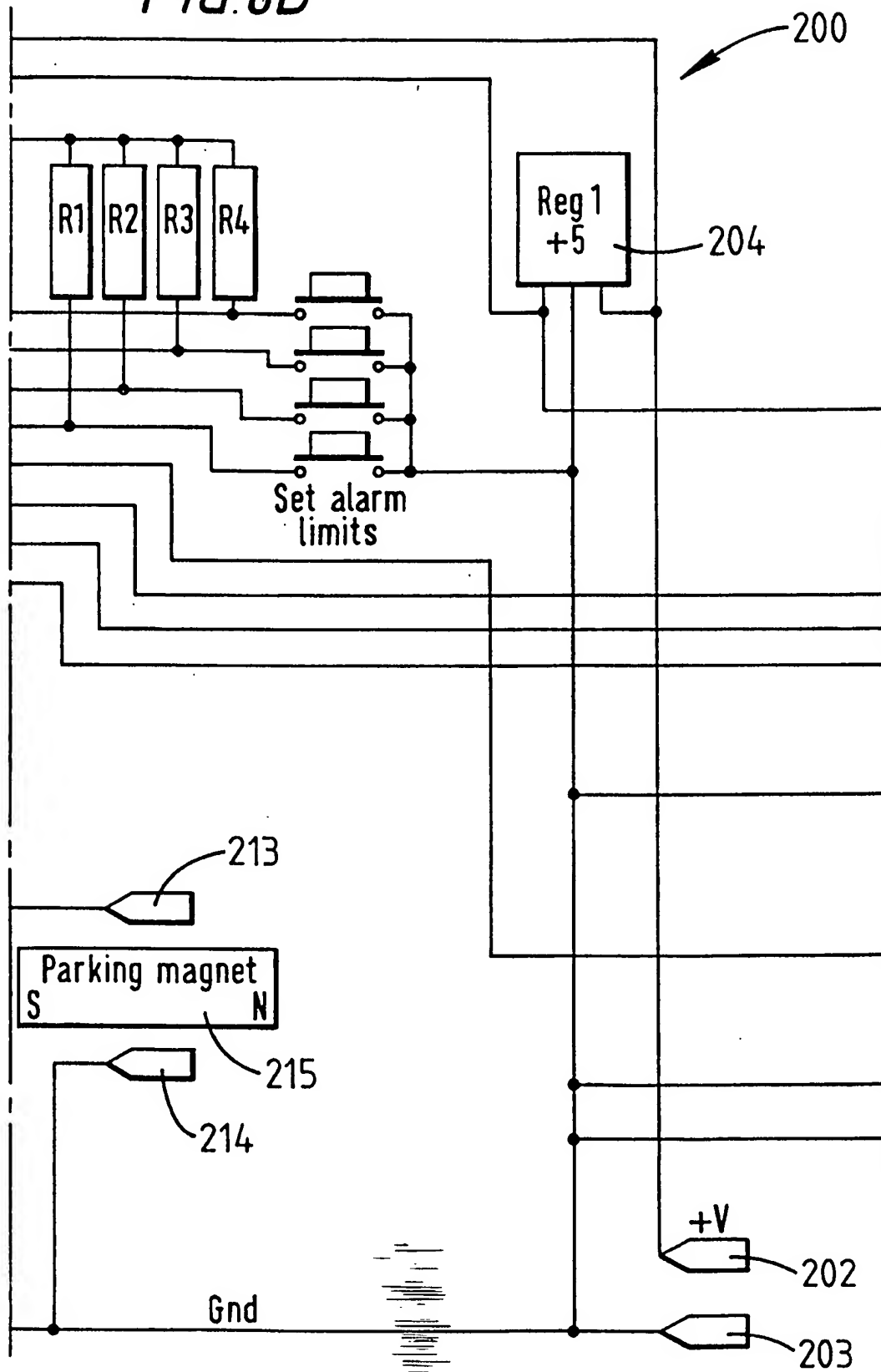
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FIG. 8A



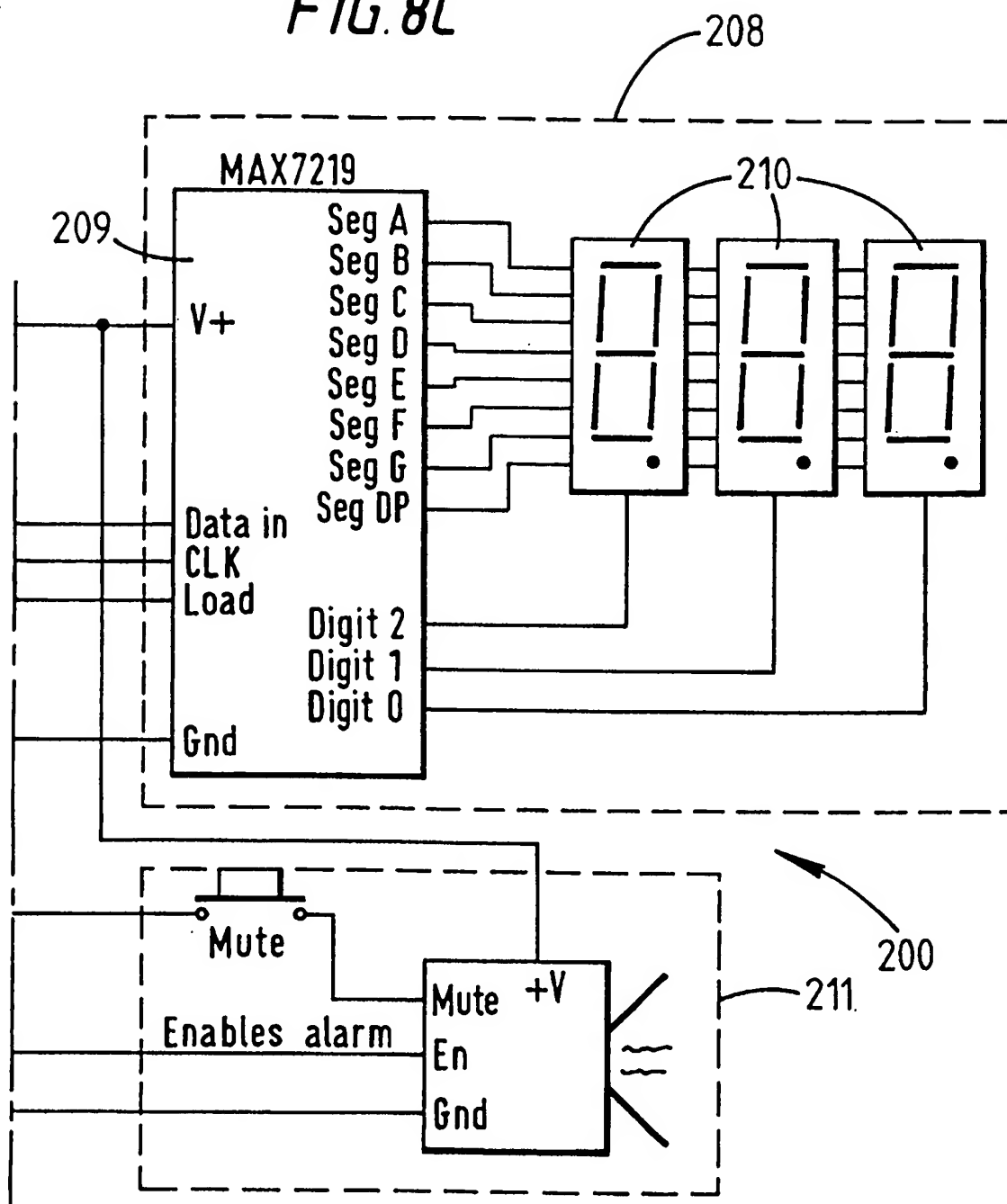
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FIG. 8B



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FIG. 8C



INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 98/02765

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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A	see column 4, line 47 - column 6, line 64; tables 1-3 ---	4,7,18, 23
X	WO 93 08734 A (MAGILL ALAN REMY) 13 May 1993	1-4,6,8, 11-13,17
A	see page 6, line 16 - page 13, line 20; tables 1-5 ---	5,15,16, 23,29-31
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A	see column 1, line 55 - column 3, line 66; tables 1-4 ---	9,10,17
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

5 January 1999

Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

Int. J. Application No

PCT/GB 98/02765

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